REMARKS

The present amendment is intended to be fully responsive to the Office Action having a mailing date of August 22, 2007, wherein claims 1, 2, 4-11, 13-17, 19-21, 23-34, 36-42 and 50 have been rejected and are currently pending. By this amendment, claims 1, 7, 8, 16, 20, and 34 have been amended. Claim 13 has been canceled. Thus, claims 1-2, 4-11, 14-17, 19-21, 23-34, 36-42, and 50 remain pending. New claims 51 and 52 have been added. Support for claims 51 and 52 may be found in at least paragraph [0027]. Indeed, Applicant submits that no new matter has been added by this amendment and that support for the claims, as amended, may be found throughout the specification and drawings.

At least for the reasons set forth below, Applicant respectfully traverses the foregoing rejections. Further, Applicant believes that there are also reasons other than those set forth below why the pending claims are patentable, and reserve the right to set forth those reasons, and to argue for the patentability of claims not explicitly addressed herein, in future papers. Applicants respectfully requests reconsideration of the present application in view of the above amendment, the new claims, and the following remarks.

35 U.S.C. § 112

Claims 1 and 7 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. More specifically, the Examiner argues that there is no support in the specification for the limitation that the cannula can only accommodate one of the introducer stylet and target confirmation device at a time. Applicant respectfully disagrees.

MPEP § 2181 (IV) recites, in part "[i]n considering whether there is 35 U.S.C. 112, first paragraph support for the claim limitation, the examiner must consider not only the original disclosure contained in the summary and detailed description of the invention portions of the specification, but also the original claims, abstract, and drawings." *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1564 (Fed. Cir. 1991) (emphasis added). Thus, the drawings may be used to provide antecedent basis for the claimed subject matter.

As is clearly shown in at least the embodiment depicted in Figures 7-9, only one of the separate target confirmation device and the introducer stylet may be disposed within the introducer cannula at a time. Similarly, as shown in the embodiment depicted in Figure 1, the relative sizes of the introducer stylet and separate target confirmation device with respect to the inner diameter of the introducer cannula also provides support for the limitations set forth in claims 1 and 7. For at least these reasons, Applicant respectfully requests withdrawal of the rejection.

35 U.S.C. § 103

A. Claim Rejections Using *Balbierz* alone

Claims 1, 2, 6, 13-17, 20, 25 and 33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz (U.S. Patent No. 6,869,430), hereinafter Balbierz ('430). Applicants respectfully traverse the rejection.

Independent claim 1 positively recites an introducer stylet and a separate target confirmation device. Further, the introducer stylet of claim 1 is "generally linear" in configuration and includes a tissue piercing tip on the distal end thereof. Support for these amendments may be found in at least paragraph [0020] and Figure 1. Additionally, the introducer stylet of claim 1 is "configured for penetrating tissue." Applicant respectfully asserts that these features are not shown in Balbierz.

Balbierz discloses a "tissue biopsy and treatment apparatus 10" that is configured for "volumentrically sampling the issue mass and delivering energy or other treatment to produce an ablation volume 5av." Col. 5, lines 25-30. The *biopsy treatment apparatus 10* includes an introducer 12 having a lumen 13 and a plurality of "resilient members 18 positionable within lumens 13". Col. 5, lines 31-34. The distal end 16 of the introducer 12 "may be sufficiently sharp to penetrate tissue . . . " Col. 5, lines 36-37. Thus, Balbierz discloses that the cannula of the *biopsy device 10* is used to penetrate tissue, not the resilient members. Nor is there any such disclosure that the resilient members are "configured for penetrating tissue" as positively claimed by Applicants.

Nor is there any teaching or suggestion that the resilient members of Balbierz include a "tissue piercing tip" as recited in claim 1. Indeed, Balbierz teaches away from this configuration as the distal end of the introducer cannula of the biopsy device is used to penetrate tissue. Col. 5, lines 36-37. Thus, for at least this reason, claim 1 patentably defines over Balbierz.

Further, claim 1 has been amended to recite that the claimed introducer stylet of claim 1 is configured to be "generally linear." Support for this amendment may be found in at least Figure 1 of the application, as originally filed. In contrast, the "resilient members" of Balbierz are not configured to be generally linear. Indeed, the "resilient members" of Balbierz are configured to be "deployed with curvature from introducer 12." Col. 5, lines 44-46. Thus, Balbierz teaches away from claim 1. For at least this reason, claim 1 is not obviated by Balbierz.

Finally, as expressly acknowledged by the Examiner, Balbierz does not disclose or even suggest an introducer stylet and a separate target confirmation device. Indeed, the Examiner refers to the same resilient members "as serving as both an introducer stylet and target confirmation device." Further, the Examiner also states (without any reference to the prior art) that "Applicant's invention [would] work equally well with either sequentially or simultaneously disposed elements." Applicant respectfully disagrees. As set forth in claim 1 and in the description of one of the embodiments disclosed in the specification, the introducer stylet is configured for penetrating tissue to create a pathway to the target tissue. Once the pathway is created *and the introducer stylet is removed from the introducer cannula*, the separate target confirmation device of claim 1 is inserted into the introducer cannula to confirm the location of the target lesion. See, paragraphs [0034-0035]. In other words, the introducer stylet of claim 1 creates the pathway the permits the separate target confirmation device to reach the target lesion. Thus, the sequential disposal of the introducer stylet and separate target confirmation device of claim 1 are not "mere design choices."

Further, Balbierz does not disclose or suggest an introducer that may be selectively and *removably* positioned within the lumen of the outer cannula. As may be seen in Applicants' specification, the introducer stylet embodied in claim 1 may be completely removed from the outer cannula to permit introduction of the target confirmation device. Balbierz, however, does not

disclose this feature. Instead, Balbierz only discloses that the resilient members may be "advanceable *in and out of distal end 16*." Nowhere does Balbierz teach or suggest that the resilient members may be selectively removed from an inner lumen of an outer cannula to permit an additional and separate target confirmation device to be inserted therein. For this additional reason, claim 1 is patentably distinct from Balbierz.

The dependent claims, namely claims 2, 6, 14-17, 20, 25 and 33 are allowable over Balbierz due to their dependency upon allowable claim 1. However, these claims also contain additional features and limitations that independent define over Balbierz. For example, Claim 16 recites that the target confirmation device includes a proximal end having a first fitting interface that engages and connects to a second fitting interface on the introducer cannula upon insertion of the target confirmation device into the introducer cannula so as "to prevent relative movement between the target confirmation device and the introducer cannula." There is no teaching or suggestion in Balbierz of these features. While the Examiner points to Figure 2 for the disclose of this feature, Figure 2 does not show *any* fitting on either the target confirmation device or the introducer cannula that interfaces to prevent relative movement between the target confirmation device and the introducer cannula. Further the Examiner's reliance on Col. 6, lines 1-2 for teaching this feature also is deficient. Indeed, this passage only states that the "handpiece can be detachable and can include ports 24' and actuators 24"."

Claim 20, as amended, recites a biopsy device that includes a handpiece, an outer cannula, and an inner cannula that is disposed within the outer cannula. Balbierz does not disclose these features. Claim 20 further requires that the inner cannula includes a cutting edge at its distal end and the outer cannula includes a tissue receiving opening, whereby the cutting edge and the tissue receiving opening cooperate to sever tissue. These features are also not taught or even suggestion by Balvierz.

Claim 33 recites a tissue resection device including a tissue receiving opening "that is positioned in a sidewall of the tissue resection device," and wherein the tissue receiving opening is rotatable relative to the cannula. The device in Balbierz provides no disclosure of a tissue resection

device having a tissue receiving opening in a sidewall of the tissue resection device. Nor does it provide any disclosure that the tissue receiving opening is rotation relative to the cannula. The passage of Balbeirz cited by the Examiner, namely col. 17, lines 57-63 does not discuss these features. Indeed, this passage is directed to a collection devices, fluid delivery devices, fluid reservoirs or power sources, not a tissue resection device with a tissue receiving opening located in a sidewall thereof as expressly claimed by Applicant. Moreover, there is simply no teaching in Balberiz of a "rotatable tissue-receiving opening" as asserted by the Examiner.

B. Claim Rejections Using *Balbierz* in view of *Hurtak*

Claims 4, 5, 7-11, 19, 26, 28, 34, 42 and 36-39 were rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz ('430) in view of Hurtak (WO 98/55016), herein after Hurtak ('016). Applicants respectfully traverse the rejection.

1. Claims 4, 5, 19, and 36-39.

As an initial matter, the arguments presented above in connection with the §103 rejection in view of Balbierz alone, are equally applicable here. And Hurtak does not make up for the deficiencies of Balbierz. For example, Hurtak does not disclose an introducer stylet having the features recited in claim 1 from which claims 4, 5, 9 and 36-39 depend. Indeed, Hurtak simply teaches a medical guidewire for use in intravascular medical procedures upon which catheters are positioned over and disposed through a vascular system.

In addition, one of ordinary skill in the art would not have had any reason to combine Balbierz and Hurtak in the manner required to obtain the claimed invention. *See KSR Int'l v. Teleflex, Inc.*, 127 S.Ct. 1727, 1741 (2007)("[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements **in the way that the claimed invention does**") (emphasis added). However, one of ordinary skill in the art would not have been motivated to combine Balbierz with Hurtak in the manner of the claims, as the

"introducer" is "steerable" and contain fiber optics (including imaging fibers). Thus, one of ordinary skill in the art armed with the teachings of Balbierz would have no need to look to a guidewire for target confirmation, as the introducer could be provided with fiber optics to image a site of interest.

2. Independent Claim 7

As an initial matter, Applicant again notes that the Examiner has rejected independent claim 7 under 35 U.S.C. 103(a) as being unpatentable over Balbierz in view of Hurtak. See, paragraph 6 of the Office Action. However, despite Applicant's previous request that the Examiner provide the required analysis as to how the Examiner is applying the references to independent claim 7, the Examiner has again failed to provide any insight as to how claim 7 is rendered unpatentable in view of the combination. Indeed, like the previous office action, the present office action fails to even discuss claim 7.

Notwithstanding the fact that the Examiner has failed to meet its burden in setting forth a prima facie case of obviousness, a review of teachings of Balbierz and Hurtak make clear that claim 7 is patentable over the combination. Indeed, claim 7 specifically requires an introducer cannula, an introducer stylet, a separate target confirmation device, and a separate biopsy device. The claimed biopsy device recited in claim 7 requires an outer cannula and an inner cannula disposed therein, whereby the inner cannula of the biopsy device includes a cutting edge for severing tissue and the outer cannula is configured for selective insertion within introducer cannula. These features are not taught or shown in Balbierz, alone or in combination with Hurtak.

Indeed, Balbierz discloses a "tissue biopsy and treatment apparatus 10" that is configured for "volumentrically sampling the issue mass and delivering energy or other treatment to produce an ablation volume 5av." Col. 5, lines 25-30. The biopsy treatment apparatus 10 includes the introducer 12 having a lumen 13 and a plurality of "resilient members 18 positionable within lumens 13". Col. 5, lines 31-34. Thus, Balbierz discloses that the *biopsy device* includes the cannula having lumens into which the "resilient members 18" are positioned. Balbierz certainly

does not provide any disclosure of positioning a biopsy device within a separate introducer cannula whereby the *biopsy device* includes outer and inner cannulas, nor is there any disclosure of an inner cannula of a biopsy device having a cutting edge for severing tissue as positively claimed in claim 7. Hurtak does not disclose a biopsy device and thus cannot make up for the deficiencies of Balbierz. Thus, for at least these reasons, claim 7 is not obviated by the Balbierz and Hurtak combination.

3. Dependent Claims 8-11, and 34

Claims 8-11 and 34 depend from claim 7. Accordingly, these claims are patentable by virtue of their dependency upon claim 7. However, these claims contain additional limitations that are not show or suggested by either Balbierz, alone or in combination with Hurtak. For example, claim 9 requires that the distal end of the target confirmation device has a predetermined shape. This feature is not taught or suggestion in either Balbierz or in Hurtak. Nor has the Examiner pointed to any teaching or suggestion of any such feature.

Claim 34 requires that the claimed biopsy system includes a tissue receiving opening positioned in a sidewall of the outer cannula of the biopsy device adjacent a distal end thereof. The device in Balbierz provides no disclosure of an outer cannula having a tissue receiving opening in a sidewall of the outer cannula of the biopsy device. Nor does it provide any disclosure that the tissue receiving opening is rotatable relative to the introducer cannula. The passage of Balbeirz cited by the Examiner, namely col. 17, lines 57-63 does not discuss these features. Indeed, this passage is directed to a collection devices, fluid delivery devices, fluid reservoirs or power sources, not a biopsy device with a tissue receiving opening located in a sidewall thereof as expressly claimed by Applicant. Moreover, there is simply no teaching in Balberiz of a "rotatable tissue-receiving opening" as asserted by the Examiner.

4. Independent Claim 26

As an initial matter, Applicant notes that the Examiner has rejected independent claim 26 for the second time under 35 U.S.C. 103(a) as being unpatentable over Balbierz in view of Hurtak. See, paragraph 6 of the Office Action. However, despite Applicant's previous request that the Examiner provide the required analysis as to how the Examiner is applying the references to independent claim 26, the office action is silent as to how any of the references render independent claim 26 unpatentable. Indeed, like the previous office action, the present office action fails to even discuss claim 26.

Notwithstanding the Examiner's failure to provide any citation or support for the rejection of claim 26, Applicant asserts that neither Balbierz, nor Hurtak, alone or in combination, obviate the claimed invention that is the subject of claim 26. Indeed, claim 26 requires inserting an introducer stylet into an outer cannula such that a distal end of the introducer stylet extends substantially away from a distal end of the of the outer cannula *and then* inserting the introducer stylet with the outer cannula thereon, into a patient's body to create a pathway to a target tissue. As the stylet is is disposed away from the distal end of the outer cannula, it penetrates the tissue to create the pathway, while carrying the outer cannula. Next, the introducer stylet is removed from the patient's body, but the outer cannula is specifically let in the patient's body and a separate target confirmation device is then inserted into the patient's body, through the outer cannula to confirm the location of the target tissue. None of these features are taught or suggested by the prior art of record. Indeed, Balbierz teaches away from Applicant's invention embodied by claim 26 in that the cannula 12 of the biopsy deivce of Balbierz is used to penetrate the patient's tissue. Col. 5, lines 36-37. Thus, Balbierz does not obviate claim 26.

And Hurtak does not make up for the deficiencies of Balbierz. Hurtak only discloses a guidewire for intravascular applications. As guidewires are deployed through the vascular system, there is no need to create a pathway to a target site.

5. Dependent Claims 28 and 42

Claims 28 and 42 are dependent upon claim 26. Thus, the arguments presented above in connection with claim 26 is equally applicable here. Thus, these claims are patentable by virtue of their dependency upon claim 26. Moreover, these claims are independently patentable. For example, claim 42 requires the step of removing the target confirmation device and inserting a biopsy device that includes a tissue receiving opening into the introducer cannula. This feature is not taught or even suggested by Balbierz. Indeed, Balbierz teaches away from this method as the "cannula" in Balbierz is part of the biopsy device. Moreover, the passage cited by the Examiner (col. 17, lines 57-63) is directed to coupling tissue aspiration/collection devices 26 to a handpiece. There is no teaching or suggestion of *inserting a biopsy device* into the introducer cannula as positively recited by Applicants.

C. Claim Rejections Using *Balbierz* in view of *Hurtak*, further in view of *Werne*

Claims 21, 23, 24, 27, 29-32, 41 and 50 were rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz ('430) in view of Hurtak ('016), further in view of Werne (U.S. Patent No. 5,782,764). Applicants respectfully traverse the rejections.

The discussion above with respect to the previous rejections using Balbierz and Hurtak are equally applicable to this rejection. Thus, these claims are patentable by virtue of their dependency upon allowable independent claims. Moreover, Applicant respectfully disagrees with the Examiner's characterization of the teachings of the Bablierz/Hurtak/Werne combination as pointed out in the above sections and the previous office action responses.

D. New Claims 51 and 52

Claims 51 and 52 have been added. Claim 51 is directed to a breast biopsy system for use with a magnetic resonance imaging (MRI) device. Claim 51 specifically provides for "a unitary introducer and target confirmation stylet" in contrast to claims 1 and 7 wherein the stylet and target confirmation devices are separate elements. Support for this limitation may be found in at least

paragraph [0027]. In addition to this limitation, claim 51 further requires a biopsy device having an outer cannula and an inner cannula, that are inserted into an introducer cannula. The recited limitations of the biopsy device are not taught, shown or suggested by the prior art of record as discussed above in connection with the discussion regarding claim 20, for example.

Claim 52 is a method claim using a unitary introducer and target confirmation stylet and a biopsy device having the same limitations recited in claim 51. Thus, claim 52 is also patentably distinct from the prior art of record.

CONCLUSION

Reconsideration and allowance are respectfully requested. In view of the above, each of the presently pending claims in this application is believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Any fees due with this response are identified in an accompanying transmittal. However, if any additional fees are due, please charge our Deposit Account No. 18-0013, under Order No. 65937-0037 from which the undersigned is authorized to draw.

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Respectfully submitted,

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